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| APPLICATION NO.        | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|-------------|----------------------|---------------------|------------------|
| 09/846,637             | 04/30/2001  | Michael C. Jensen    | 24751-2502          | 4845             |
| 34055                  | 7590        | 03/19/2004           | EXAMINER            |                  |
| PERKINS COIE LLP       |             |                      | PAK, YONG D         |                  |
| POST OFFICE BOX 1208   |             |                      | ART UNIT            |                  |
| SEATTLE, WA 98111-1208 |             |                      | PAPER NUMBER        |                  |

1652

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/846,637 | <b>Applicant(s)</b><br>JENSEN, MICHAEL C. |  |
|                              | <b>Examiner</b><br>Yong D Pak        | <b>Art Unit</b><br>1652                   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 73-74, 142-143, 190-191, 206-207, 219-220, 234-235, 248-249, 260-261 and 270-285 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**Continuation Sheet (PTOL-326)**

**Application No. 09/846,637**

Continuation of Disposition of Claims: Claims pending in the application are 23,24,27-41,50-54,63,73,74,81,82,85,141-143,166-263,265,266 and 268-285.

Continuation of Disposition of Claims: Claims rejected are 23,24,27-41,50-54,63,81,82,85,141,143,166-189,192-205,208-218,221-233,236-248,250-259,262,263,265,266,268 and 269.

### **DETAILED ACTION**

The amendment filed on December 29, 2003, canceling claims 25-26, 264 and 267, amending claims 23, 27-31, 38-39, 53-54, 63, 81, 141, 172-173, 178-179, 183-184, 188-189, 192, 196, 200-201, 205, 208, 213-214, 218, 221-223, 226, 236-237, 247, 250, 259, 262, 265-266, 268-269 and adding claims 270-285, has been entered.

Claims 23-24, 27-41, 50-54, 63, 73-74, 81-82, 85, 141-143, 166-263, 265-266 and 268-285 are pending.

### ***Response to Arguments***

Applicant's arguments filed on December 29, 2003 have been fully considered but they are not persuasive.

### ***Claim Rejections - 35 USC § 103***

Claims 23-24, 27-41, 50-54, 63, 81-82, 85, 141, 143, 166-189, 192-205, 208-218, 221-233, 236-248, 250-259 and 262-263, 265-266, 268-269 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farazi et al. in view of Roelant.

Applicants argue that there is no motivation or suggestion to combine the references for several reasons.

Applicants argue that it is difficult to screen for cells comprising a nucleic acid encoding a mutagenized enzyme that may or may not be resistant to inhibitors or conditions that inhibit the wild-type enzyme. The examiner disagrees. Farazi et al.

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teach several mutant IMPDH mutants that are resistant to inhibitors of wildtype IMPDH (abstract).

Applicants argue that Farazi et al. disclose a method of screening for mutagenized enzyme wherein the mutagenized enzyme is not known prior to the screening. This argument has no bearing since the reference of Farazi et al. is used to demonstrate teachings of mutant IMPDH that are resistant to inhibitors of wild type IMPDH and not to demonstrate teachings of making/screening for mutant IMPDH.

Applicants argue that Farazi et al. do not teach the introduction of mutant genes into eukaryotic cells. However, introduction of gene into eukaryotic cells are very well practiced and highly routine in the art. One of ordinary skill in the art would have been motivated to use eukaryotic cells such as human cells since Roelant teach cell proliferation assays with human cells and since the IMPDH of Farazi et al. is derived from human thereby providing a more native cellular environment.

Applicants argue that Roelant only teach a method of quantifying number of viable cells and not to proliferate cells. The examiner disagrees. Roelant does teach cell proliferation/cell toxicity assays in Columns 7-8.

Applicants argue that the combined references are misleading because Farazi et al. uses E. coli colonies grown on minimal media and Roelant teaches quantifying viable cells in an aqueous suspension. The examiner disagrees. Roelant teach how to prepare cells for quantifying viable cells in Columns 5-6. Again, the Farazi et al. reference was used to disclose teachings of mutant IMPDH that are resistant to

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inhibitors of wild type IMPDH and not to demonstrate teachings of making/screening for mutant IMPDH.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the mutant of Farazi et al. and screen whether these mutants have resistance against inhibitors of IMPDH by performing cell proliferation assays, quantifying viable cells containing the mutant enzymes and cell containing wildtype IMPDH using the methods of Roelant. The motivation of performing the cell proliferation assay is to determine if the mutant IMPDH are resistant to IMPDH inhibitors since inhibition of IMPDH results in anti-proliferative activity. Also, IMPDH that are resistant to its inhibitors can be useful in anti-infective chemotherapy by designing species-selective IMPDH inhibitors. One of ordinary skill in the art would have had a reasonable expectation of success since Farazi et al. teach mutant IMPDH that is resistant against its inhibitors and cell proliferation assays are performed routinely in the art.

***Allowable Subject Matter***

Claims 73-74, 142-143, 190-191, 206-207, 219-220, 234-235, 248-249, 260-261 and 270-285 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak  
Patent Examiner

March 17, 2004

  
NASHAAT T. NASHED PHD.  
PRIMARY EXAMINER